EXAMINER'S AMENDMENT

1. Applicant's Appeal Brief filed March 25, 2008 has been entered. Claims 21-46 and 48-61 are pending in the application.

2. In view of the interviews held June 12, 2008 and June 13, 2008, all rejections are withdrawn.

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph Coppola on June 13, 2008.

4. The application has been amended as follows:

In the claims:

1-20. (canceled)

21. (currently amended) A method of immunizing bovine animals against mastitis comprising administering to bovine animals at least one inactivated or attenuated *Mycoplasma bovis* biotype, whereby the clinical incidence of mastitis in the bovine animals is reduced such that the number or percentage of bovine animals that show clinical ~~symptoms of mastitis~~ *Mycoplasma bovis* infection is less after such administering than before such administering.

22. (canceled)

23. (currently amended) The method of claim ~~22~~ 21 comprising administering at least one inactivated *Mycoplasma bovis* biotype to at least about 50% of the herd.

24. (previously presented) The method of claim 21 where the inactivated or attenuated *Mycoplasma bovis* biotype is administered together with an adjuvant.

25. (previously presented) The method of claim 24 where the adjuvant is an aluminum hydroxide-oil emulsion; a mineral, vegetable, or fish oil-water emulsion; a water-oil-

water emulsion; incomplete Freund's adjuvant; *E. coli* J5; dextran sulfate; iron oxide; sodium alginate; Bacto-Adjuvant; a synthetic polymer; Carbopol; a poly-amino acid; a co-polymer of amino acids; saponin; carrageenan; N, N-dioctadecyl-N'-N'-bis(2-hydroxyethyl) propanediamine; a long chain polydispersed β(1,4) linked mannan polymer interspersed with O-acetylated groups; deproteinized cell wall extracts from a non-pathogenic strain of *Mycobacterium*; mannite monooleate; paraffin oil; or muramyl dipeptide.

26. (previously presented) The method of claim 21 where the inactivated or attenuated *Mycoplasma bovis* biotype is administered together with a pharmaceutically acceptable excipient.

27. (previously presented) The method of claim 21 where the inactivated or attenuated *Mycoplasma bovis* biotype is administered orally, intranasally, intratracheally, intramuscularly, intramammarily, subcutaneously, intravenously, or intradermally.

28. (previously presented) The method of claim 21 where the inactivated or attenuated *Mycoplasma bovis* biotype is administered by injection, inhalation, ingestion, or infusion.

29. (previously presented) The method of claim 21 where the *Mycoplasma bovis* biotype has been inactivated.

30. (previously presented) The method of claim 29 where the *Mycoplasma bovis* biotype has been inactivated by treatment with: formalin, azide, freeze-thawing, sonication, heat, sudden pressure drop, detergent, lysozyme, phenol, proteolytic enzymes, β-propiolactone, Thimerosal, or binary ethyleneimine.

31. (previously presented) The method of claim 30 where the *Mycoplasma bovis* biotype has been inactivated by treatment with β-propiolactone.

32. (previously presented) The method of claim 21 where at least two inactivated *Mycoplasma bovis* biotypes are administered.

33. (previously presented) The method of claim 32 where the at least two inactivated *Mycoplasma bovis* biotypes are selected from the group consisting of Biotype A, Biotype B, and Biotype C.

34. (previously presented) The method of claim 32 where at least 10^8 cell equivalents of each *Mycoplasma bovis* biotype are administered.

35. (previously presented) The method of claim 32 where approximately 10^8 cell equivalents of each *Mycoplasma bovis* biotype are administered.

36. (previously presented) The method of claim 32 where at least approximately 10^5 cell equivalents of each *Mycoplasma bovis* biotype are administered.

37. (previously presented) The method of claim 32 where approximately 10^5 cell equivalents of each *Mycoplasma bovis* biotype are administered.

38. (previously presented) The method of claim 32 where the at least two inactivated *Mycoplasma bovis* biotypes are administered separately.

39. (previously presented) The method of claim 21 where at least two inactivated *Mycoplasma bovis* biotypes and an antigen derived from another pathogen are administered.

40. (previously presented) The method of claim 39 where the antigen from another pathogen is from an attenuated or inactivated virus.

41. (previously presented) The method of claim 39 where the antigen from another pathogen is selected from the group consisting of antigens from *Staphylococcus aureus, Pasteurella hemolytica, Pasteurella multocida, Hemophilus somnus*, Bovine Respiratory Syncytial Virus, *E. coli*, and the organism causing Infectious Bovine Rhinotrachial Disease.

42. (previously presented) The method of claim 32 where the at least two inactivated *Mycoplasma bovis* biotypes are genetically different as determined by an analysis of DNA or RNA from the biotypes.

43. (previously presented) The method of claim 42 where the analysis is PCR fingerprinting, analysis of ribosomal RNA, or analysis of DNA polymorphisms.

44. (previously presented) The method of claim 43 where the analysis is by PCR fingerprinting.

45. (previously presented) The method of claim 44 where the PCR fingerprinting uses arbitrarily chosen primers.

46. (previously presented) The method of claim 44 where the PCR fingerprinting uses as primers 5' NNN NCG NCG NCA TCN GGC 3' (SEQ ID NO:1) and 5' NCG NCT TAT CNG GCC TAC 3' (SEQ ID NO:2).

47. (canceled)

48. (previously presented) The method of claim 32 where the at least two *Mycoplasma bovis* biotypes are administered in a specific ratio.

49. (previously presented) The method of claim 32 where the at least two *Mycoplasma bovis* biotypes are grown separately as pure cultures, inactivated, and combined together in equal amounts before being administered to the animal.

50. (currently amended) A method for immunizing bovine animals against mastitis comprising administering to bovine animals an antigenic component from at least one inactivated or attenuated *Mycoplasma bovis* biotype, whereby the clinical incidence of mastitis in the bovine animals is reduced such that the number or percentage of bovine animals that show clinical ~~symptoms of mastitis~~ *Mycoplasma bovis* infection is less after such administering than before such administering.

51. (previously presented) The method of claim 50 where antigenic components from at least two *Mycoplasma bovis* biotypes are administered.

52. (previously presented) The method of claim 21 where the administering results in greater milk production, greater weight gain, or less clinical disease in the bovine animal.

53. (currently amended) A method of immunizing bovine animals against mastitis comprising:

(a) testing samples from bovine animals for the presence of *Mycoplasma bovis* biotypes, thereby identifying specific *Mycoplasma bovis* biotypes in the samples;

(b) preparing a vaccine by inactivating at least 10^5 cell equivalents of at least one of the *Mycoplasma bovis* biotypes identified in step (a); and

(c) administering to the bovine animals the vaccine of step (b),

whereby the bovine animals are immunized so that the clinical incidence of mastitis in the bovine animals is reduced such that the number or percentage of bovine animals that show clinical ~~symptoms of mastitis~~ *Mycoplasma bovis* infection is less after such administering than before such administering.

54. (previously presented) The method of claim 53 where the sample is milk.

55. (previously presented) The method of claim 53 where step (a) comprises genetic analysis of DNA or RNA from the *Mycoplasma bovis* biotypes.

56. (previously presented) The method of claim 55 where the genetic analysis is PCR fingerprinting, analysis of ribosomal RNA, or analysis of DNA polymorphisms.

57. (previously presented) The method of claim 56 where the genetic analysis is PCR fingerprinting.

58. (previously presented) The method of claim 21 whereby the administering does not cause unfavorable reactions.

59. (previously presented) The method of claim 32 whereby the administering does not cause unfavorable reactions.

60. (previously presented) The method of claim 29 whereby the at least one inactivated *Mycoplasma bovis* biotype has not been inactivated with formalin.

61. (previously presented) The method of claim 32 whereby the at least two inactivated *Mycoplasma bovis* biotypes have not been inactivated with formalin.

Reasons for Allowance

5. The prior art does not teach or disclose a method of immunizing bovine animals against mastitis comprising administering to bovine animals at least one inactivated or attenuated *Mycoplasma bovis* biotype, whereby the clinical incidence of mastitis in the bovine animals is reduced such that the number or percentage of bovine animals that show clinical *Mycoplasma bovis* infection is less after such administering than before such administering.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/
Patent Examiner, Art Unit 1645
June 19, 2008

/N. M. Minnifield/
Primary Examiner, Art Unit 1645

CLEAN COPY OF ALLOWED CLAIMS

21. A method of immunizing bovine animals against mastitis comprising administering to bovine animals at least one inactivated or attenuated *Mycoplasma bovis* biotype, whereby the clinical incidence of mastitis in the bovine animals is reduced such that the number or percentage of bovine animals that show clinical *Mycoplasma bovis* infection is less after such administering than before such administering.

23. The method of claim 21 comprising administering at least one inactivated *Mycoplasma bovis* biotype to at least about 50% of the herd.

24. The method of claim 21 where the inactivated or attenuated *Mycoplasma bovis* biotype is administered together with an adjuvant.

25. The method of claim 24 where the adjuvant is an aluminum hydroxide-oil emulsion; a mineral, vegetable, or fish oil-water emulsion; a water-oil-water emulsion; incomplete Freund's adjuvant; *E. coli* J5; dextran sulfate; iron oxide; sodium alginate; Bacto-Adjuvant; a synthetic polymer; Carbopol; a poly-amino acid; a co-polymer of amino acids; saponin; carrageenan; N, N-dioctadecyl-N'-N'-bis(2-hydroxyethyl) propanediamine; a long chain polydispersed β(1,4) linked mannan polymer interspersed with O-acetylated groups; deproteinized cell wall extracts from a non-pathogenic strain of *Mycobacterium*; mannite monooleate; paraffin oil; or muramyl dipeptide.

26. The method of claim 21 where the inactivated or attenuated *Mycoplasma bovis* biotype is administered together with a pharmaceutically acceptable excipient.

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33. The method of claim 32 where the at least two inactivated *Mycoplasma bovis* biotypes are selected from the group consisting of Biotype A, Biotype B, and Biotype C.

34. The method of claim 32 where at least 10^8 cell equivalents of each *Mycoplasma bovis* biotype are administered.

35. The method of claim 32 where approximately 10^8 cell equivalents of each *Mycoplasma bovis* biotype are administered.

36. The method of claim 32 where at least approximately 10^5 cell equivalents of each *Mycoplasma bovis* biotype are administered.

37. The method of claim 32 where approximately 10^5 cell equivalents of each *Mycoplasma bovis* biotype are administered.

38. The method of claim 32 where the at least two inactivated *Mycoplasma bovis* biotypes are administered separately.

39. The method of claim 21 where at least two inactivated *Mycoplasma bovis* biotypes and an antigen derived from another pathogen are administered.

40. The method of claim 39 where the antigen from another pathogen is from an attenuated or inactivated virus.

41. The method of claim 39 where the antigen from another pathogen is selected from the group consisting of antigens from *Staphylococcus aureus, Pasteurella hemolytica, Pasteurella multocida, Hemophilus somnus*, Bovine Respiratory Syncytial Virus, *E. coli*, and the organism causing Infectious Bovine Rhinotrachial Disease.

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49. The method of claim 32 where the at least two *Mycoplasma bovis* biotypes are grown separately as pure cultures, inactivated, and combined together in equal amounts before being administered to the animal.

50. A method for immunizing bovine animals against mastitis comprising administering to bovine animals an antigenic component from at least one inactivated or attenuated *Mycoplasma bovis* biotype, whereby the clinical incidence of mastitis in the bovine animals is reduced such that the number or percentage of bovine animals that show clinical *Mycoplasma bovis* infection is less after such administering than before such administering.

51. The method of claim 50 where antigenic components from at least two *Mycoplasma bovis* biotypes are administered.

52. The method of claim 21 where the administering results in greater milk production, greater weight gain, or less clinical disease in the bovine animal.

53. A method of immunizing bovine animals against mastitis comprising:
(a) testing samples from bovine animals for the presence of *Mycoplasma bovis* biotypes, thereby identifying specific *Mycoplasma bovis* biotypes in the samples;
(b) preparing a vaccine by inactivating at least 10^5 cell equivalents of at least one of the *Mycoplasma bovis* biotypes identified in step (a); and
(c) administering to the bovine animals the vaccine of step (b),
whereby the bovine animals are immunized so that the clinical incidence of mastitis in the bovine animals is reduced such that the number or percentage of bovine animals that show clinical *Mycoplasma bovis* infection is less after such administering than before such administering.

54. The method of claim 53 where the sample is milk.

55. The method of claim 53 where step (a) comprises genetic analysis of DNA or RNA from the *Mycoplasma bovis* biotypes.

56. The method of claim 55 where the genetic analysis is PCR fingerprinting, analysis of ribosomal RNA, or analysis of DNA polymorphisms.

57. The method of claim 56 where the genetic analysis is PCR fingerprinting.

58. The method of claim 21 whereby the administering does not cause unfavorable reactions.

59. The method of claim 32 whereby the administering does not cause unfavorable reactions.

60. The method of claim 29 whereby the at least one inactivated *Mycoplasma bovis* biotype has not been inactivated with formalin.

61. The method of claim 32 whereby the at least two inactivated *Mycoplasma bovis* biotypes have not been inactivated with formalin.